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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/539,627	09/19/2005	Knut Adermann	P70650US0	2753

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JACOBSON HOLMAN PLLC
400 SEVENTH STREET N.W.
SUITE 600
WASHINGTON, DC 20004

EXAMINER	
AUDET, MAURY A	

ART UNIT	PAPER NUMBER
1654	

MAIL DATE	DELIVERY MODE
05/16/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/539,627	ADERMANN ET AL.	
	Examiner	Art Unit	
	MAURY AUDET	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *5/7/07*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *22-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *29-34* is/are allowed.

6)☒ Claim(s) *22-28* is/are rejected.

7)☒ Claim(s) *22-36* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *17 June 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The present application was transferred from former Examiner Young to the present Examiner.

Applicant's amendment adding new claims 22-36 and response thereto are acknowledged. The claims remain examined only as drawn to the elected compound of the invention SEQ ID NO: 86.

Election/Restrictions

As stated previously, Applicant's election with traverse of Group I, claims 1-10, 13-17, and 20 (products), as drawn to the elected peptide of the invention (NOT species) of SEQ ID NO: 86, in the reply filed on 5/7/07 is acknowledged. The traversal is on the ground(s) that the previous Examiner did not establish proper grounds for Lack of Unity under 371 practice and thus restriction of the invention. This is not found persuasive for the reasons of record. Unless Applicant should wish to put forth, on the record, that art upon any of the presently deemed distinct peptides in turns render obvious any other distinct peptide therein – in other words, the peptides are not distinct from one another. Should the latter be presented before this Examiner, in the response hereto, this Examiner is willing to open up the search to the entire gamet of peptides herein, irrespective of any undue burden associated therewith. Absent such admission, the previous Examiner's grounds are maintained and deemed proper.

The requirement is still deemed proper and is therefore made FINAL.

Claims 11-12, 18-19, and 21 are withdrawn from consideration as being drawn to nonelected subject matter. Claims 1-10, 13-17 and 20 are examined on the merits as drawn to the elected peptide of the invention: SEQ ID NO: 86.

Claim Objections

Claims 22-36 are objected to because of the following informalities: the claims have not been amended commensurate in scope with the elected invention. Namely, claim 22 retains language to "conservative variants" of SEQ ID NO: 86. The restriction requirement by the former Examiner required, to which Applicant elected SEQ ID NO: 86, a single peptide as the invention. Even a single conservative variant therein no longer makes the peptide sequence SEQ ID NO: 86. Thus, Applicant is required to delete said non-elected subject matter.

Appropriate correction is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 35 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966). The claim has been examined solely as product (SEQ ID NO: 86).

35 U.S.C. 112, 1st Enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The rejection of new claims 22-28 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement, is maintained for the reasons of record. Applicant's arguments have been considered but are not found persuasive. Namely, although the compound shows promise for treating HIV infection, the reality is that the biological, *in vivo* application of this compound has not been adequately shown either via model or phase trial.

The rejection is repeated below for continuity of record:

The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

> The first paragraph of 35 U.S.C. 112 states, "The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same...". The courts have interpreted this to mean that the specification must enable one skilled in the art to make and use the invention without undue experimentation. The courts have further interpreted undue experimentation as requiring "ingenuity beyond that to be expected of one of ordinary skill in the art" (Fields v. Conover, 170 USPQ 276 (CCPA 1971)) or requiring an extended period of experimentation in the absence of sufficient direction or guidance (In re Colianni, 195 USPQ 150 (CCPA 1977)). Additionally, the courts have determined that "... where a statement is, on its face, contrary to generally accepted scientific principles", a rejection for failure to teach how to make and/or use is proper (In re Marzocchi, 169 USPQ 367 (CCPA 1971). Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112,

> first paragraph, have been described in In re Colianni, 195 USPQ 150, 153 (CCPA 1977), have been clarified by the Board of Patent Appeals and Interferences in Ex parte Forman, 230 USPQ 546 (BPAI 1986), and are summarized in In re Wands (858 F2d 731, 737, 8 USPQ2d 1400, 1404 (Fed Cir. 1988). Among the factors are the nature of the invention, the state of the prior art, the predictability or lack thereof in the art, the amount of direction or guidance present, the presence or absence of working examples, the breadth of the claims, and the quantity of experimentation needed.

The instant disclosure fails to meet the enablement requirement for use of SEQ ID NO: 2 to treat HIV infection(s), or the following reasons:

The nature of the invention: The claimed invention is described above, SEQ ID NO: 2 for use in a medicament for treating HIV infection(s).

The state of the prior art and the predictability or lack thereof in the art: SEQ ID NO: 2 is an artificial peptide sequence, which was not found to be reasonably taught or suggested by the prior art of record. Thus, the peptide has no literature background as to effect on one more pathways associated with HIV infection(s). However, what is known is that HIV infection has been present in society for at least 30 years, with limited success being found in targeting the infection (e.g. the virus).

The amount of direction or guidance present and the presence or absence of working examples: Enablement must be provided by the specification unless it is well known in the art. *In re Buchner* 18 USPQ 2d 1331 (Fed. Cir. 1991). The drawings are drawn to e.g. tests on hemolysis. None were found to exhibit studies directly on HIV infection interaction between SEQ ID NO: 2 and the virus associated with HIV. Applicant concludes (page 36) that based on the results of the hemolysis tests: These results demonstrate that peptides of the invention block cellular infection by HIV particles by interacting with the viral gp41 protein. SEQ ID NO: 2 appears to have impact as to pathways associated with HIV, but not with the virus directly.

The breadth of the claims and the quantity of experimentation needed: Given the breadth of the claims to use SEQ ID NO: 2 to treat HIV infections, and absent sufficient teachings in the specification to overcome the teachings of unpredictability found in the art; namely as to whether the ability to treat certain pathways associated with HIV (though not the virus itself) are truly enabling for treating the virus? Absent evidence to the contrary, merely treating such pathways is not deemed to treat per se, the HIV virus (e.g. infection) and it would require undue experimentation by one of skill in the art to be able to practice the invention commensurate in scope with the claims, of using SEQ ID NO: 2 to treat the HIV virus. [The present rejection is made irrespective of the elected invention being to products (SEQ ID NO: 2), and the above merely intended use of SEQ ID NO: 2 (as opposed to actual methods of use thereto)].

Claim Rejections - 35 USC § 112 2nd

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 35 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 35 provides for the use of a peptide of SEQ ID NO: 86, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Double Patenting

Claim 36 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 29. As product claims, there are no further structural limitations to the latter v. the former. They are the same product, and claim 29, as noted below, has been indicated as allowable. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Claims 29-34 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MAURY AUDET whose telephone number is (571)272-0960. The examiner can normally be reached on M-Th. 7AM-5:30PM (10 Hrs.).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MA, 5/9/2008

/Andrew D Kosar/
Primary Examiner, Art Unit 1654